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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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GAYLE, et al.,

Plaintiffs, New York, N.Y.

v. 19 CV 3451 (WHP)

PFIZER, INC., et al.,

Defendants.

----------x Motion

December 13, 2019
3:00 p.m.

Before:

HON. WILLIAM H. PAULEY III,

District Judge

APPEARANCES

EXCOLO LAW
Attorneys for Plaintiffs
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DECHERT, LLP
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BY: LINCOLN WILSON
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THE DEPUTY CLERK: Barbara Gayle, et al. v. Pfizer, et al.

Appearances.

MR. ALTMAN: Good afternoon, your Honor. Keith Altman on behalf of the plaintiffs.

THE COURT: Good afternoon, Mr. Altman.

MR. WILSON: Good afternoon. Lincoln Wilson with Dechert LLP for Pfizer.

MS. CUSKER GONZALEZ: Mara Cusker Gonzalez from Dechert for Pfizer.

THE COURT: This is oral argument on the defendant's motion for judgment on the pleadings.

Do you want to be heard, Mr. Wilson.

MR. WILSON: Yes, your Honor.

So, good afternoon, your Honor. As you know, we're here on Pfizer's motion for judgment on the pleadings, essentially a motion to dismiss the claims of plaintiffs in this action who allege that they developed type 2 diabetes due to taking Pfizer's medication Lipitor.

In the course of briefing this motion, plaintiffs responded by offering a proposed amended complaint. And as the Court knows from our filing of our reply brief, we take the position that that proposed amendment is futile, and for that reason, dismissal with prejudice is appropriate at this juncture.

So, the crux of Pfizer's motion here is really that plaintiffs are caught between the horns of a dilemma, where, on the one hand, any claims that they have that accrued after the 2012 label change with Lipitor are barred by federal preemption, but any claims that accrued before June 2016 are barred by the statute of limitations. So, under any scenario, any claim is preempted. The plaintiffs here haven't alleged the dates on which they were diagnosed with diabetes. But because under any scenario, their claims are barred, we believe the dismissal with prejudice is proper.

And that's true in this case, because of the timing of the filing of this lawsuit in relation to the regulatory history of Lipitor and in relation to the prior litigation that's occurred about Lipitor. In the prior conference that we had in this case, we discussed some of that history, but just to recap briefly.

Lipitor is a prescription medication that's approved to treat hypercholesterolemia and other conditions, and in 2012, the FDA completed an extensive review of various data related to Lipitor, including data related to the incidence of diabetes in patients taking Lipitor. And the FDA issued a label change for Lipitor relating to those alleged risks, noting that there had been reports of increases in glucose or HBA1c as a result or in patients taking Lipitor. Following that, there was a massive filing of litigation.

THE COURT: When the FDA approved the label change to include a warning about HBA1c, does that also include diabetes?

MR. WILSON: Well, your Honor, in this case the data that the FDA was considering did relate to reports of diabetes and studies about diabetes. These materials are judicially noticeable. They are part of the FDA's file. We've referenced some of them in our motion, but we would be happy to provide an additional submission.

Notably, there is an extensive medical review report that's publicly available from the FDA, it indicates the studies that the FDA reviewed in the course of making its determination. And noted that they were the studies, for example, they include the Jupiter study which reported an increase in the investigative reported diabetes in patients that were on a related statin Crestor. This was something that the FDA was considering risks related to diabetes in the course of making that evaluation. And for that reason, we think that the initial burden of showing that the FDA has considered this risk, has been met.

THE COURT: Excuse me one moment.

You may continue, Mr. Wilson. Thank you.

MR. WILSON: Thank you, your Honor. So, because of the FDA having considered that risk, we feel our initial burden has been met. And for the plaintiffs to prove that they're able to overcome a defense of federal preemption, they would

have to show newly acquired information that was not submitted to the FDA that postdated that 2012 label change, and that was of a different kind or degree or duration or frequency than the information that the FDA already did consider, in order to prove it's even possible for Pfizer to have changed the label to something other than what the Lipitor label was. And because plaintiffs have not pled such information, we believe that their claims are preempted.

This is something there's now been quite a bit of litigation about. The newly acquired information standard is not new. It is at 21 CFR 314.3(b). And the Second Circuit actually considered this issue earlier this year in the *Gibbons* case that's cited in our briefing. And the Second Circuit was reviewing a similar complaint where the plaintiffs were trying to overcome that preemption defense, and they pleaded the existence of various studies in a very general and conclusory manner that they said were not submitted to the FDA.

THE COURT: Why don't the plethora of incident reports constitute newly acquired information?

MR. WILSON: That's for a few reasons, your Honor. The first is that the complaint here in this case, it alleges the existence of those incident reports but doesn't allege, even in a conclusory manner, much less with facts actually supporting it, that those incident reports showed a difference in degree or severity or frequency of the effect being

experienced. That's something these incident reports, these adverse event reports, Pfizer's required to submit them any time it comes into information about the report of someone who has been taking Lipitor and experiences an adverse event -- yes.

THE COURT: You may proceed.

MR. WILSON: Notably, among other things, the adverse event reports that Pfizer's required to make include when it is served with a lawsuit from someone alleging that they have developed diabetes from Lipitor. If Pfizer comes into that information, it's required to report it to the FDA. So we shouldn't be surprised that after 5,000 or 6,000 lawsuits were filed alleging type 2 diabetes due to Lipitor, that 5,000 or 6,000 reports were submitted to the FDA. It's not remarkable. And without any additional factual allegations suggesting that this is different in severity or different in degree or frequency, then there is not basis to think there is newly acquired information here.

And the Second Circuit was considering similar information in the *Gibbons* case when it held that the plaintiffs had not pled sufficient information to meet the newly acquired information standard. It was looking at similar allegations about these reports. In fact, the plaintiffs there didn't just allege reports, they also alleged studies, which haven't been alleged by the plaintiff here. And yet the Second

Circuit said it was insufficient without more to overcome the burden of preemption.

Judge Cote reached a similar conclusion in the *Utts* case. She went through a very granular analysis of the information that had been alleged by the plaintiffs and held it didn't meet that standard. And Judge Dearie of the Eastern District also reached the same conclusion in the *McGrath* case where there were similar allegations, and the Court really parsed through everything, which we think is the appropriate standard of review here, because this can be decided on the pleadings, and decided that the allegations of the plaintiffs didn't plausibly allege any information that was different in degree or severity that could have met that standard.

THE COURT: In Pfizer's view, could adverse event reports ever constitute newly acquired information?

MR. WILSON: Well, the Supreme Court, your Honor, in *Wyeth v. Levine* held that adverse event reports, if there is an analysis of those adverse event reports that would meet the newly acquired information standard, that it could meet the newly acquired information standard where there is something in the analysis that shows a difference in degree or severity. But the plaintiffs haven't alleged either the existence of that analysis or that anything about the trickling in of these adverse event reports, specifically litigation-based reports following a label change, would meet that standard.

So we think they've come far short of meeting the standard that the Supreme Court would require in the *Wyeth v. Levine*.

Now, that leads me to the second reason that the plaintiffs' claims are barred, which is that even if some of these plaintiffs -- and we don't know when their claims arose. But even if some of them arose before the 2012 label change so they were not barred by preemption, this lawsuit was filed in 2019. And so they are far beyond the date at which they would be able to timely plead their claims. New York statute of limitations applies under the borrowing statute. And New York is, as your Honor may be familiar, it's got a fairly complex discovery rule. But it starts with the simple proposition that the statute of limitations runs three years from the date of the discovery of the injury.

So these plaintiffs discovered their injury no later than the date they were diagnosed with diabetes, and their claims would be expired if they -- any claim later than June -- sorry, April 2016 would be time barred under the statute of limitations.

Now, the exceptions that New York allows for that haven't been met here. There's two exceptions that are potentially relevant here. The first is fraudulent concealment. Plaintiffs have not attempted to plead with the particularity required by Rule 9(b) any allegations that would

meet the fraudulent concealment standard, that would the require specific representations by Pfizer, reliance by the plaintiffs that would delay them in filing their claims.

In fact, even their proposed amended complaint doesn't attempt to meet that particularity standard, it doesn't allege any of the sort who, what, where, when, and why of fraud that would be required to meet that standard.

And the statutory exception to the discovery rule here is complex, but when you get down to it, it's both inapplicable and it's unavailing to the plaintiffs. New York's statutory exception to the discovery rule says that if the plaintiff discovers the cause of the injury no more than five years from the discovery of the injury itself, then plaintiff has one year from the discovery of the cause to file the lawsuit, but only if the plaintiff pleads and proves the existence of -- scientific information that was available at the time was not sufficient for them to file their claim timely. And that's CPLR 214(c).

So, when you break that down, that gives you a maximum of six years in which you would be able to potentially file a claim. But six years back from 2019 when this action was filed is 2013. And they don't get back to the point where they would be able to plead a claim that was not preempted. And in any event, plaintiffs have not pled the facts that would be required to sustain the applicability of that exception. That

exception requires them to plead "technical, scientific, medical knowledge and information was not sufficient to ascertain the cause of their injury on a timely basis." And the reason that plaintiffs -- first of all, they haven't pled the existence of such information. They haven't pled plausibly what that information was that they needed in order to file their claims.

And second, the litigation history in this action shows that it's impossible for them to plead that information. Because here, when this massive wave of lawsuits was filed back in 2013, you had a gigantic MDL formed in the District of South Carolina. It was widely publicized, plaintiffs were being brought in from around the country, thousands of plaintiffs sued both in federal courts and in various state courts around the country. The MDL court ultimately dismissed everything due to lack of expert evidence on causation, and the Fourth Circuit affirmed that in 2018.

In addition, plaintiffs' counsel here was part of this prior Lipitor litigation and has been filing Lipitor lawsuits since at least 2015. And in light of that, plaintiffs' counsel can't come in here and say that there wasn't sufficient scientific knowledge to allege diabetes from Lipitor when he's been filing those lawsuits for the last four years. It's simply not a plausible allegation, and these matters that are subject to judicial notice refute it.

So, we think ultimately plaintiffs are caught between these two horns of the dilemma. If the claims accrued before I think it's April 2016, they are barred by the statute of limitations, but after I think it's February 2012, they are barred by preemption.

Lastly I'd just note that we filed an additional point on plaintiffs' consumer protection and fraud claims. And plaintiffs did not appear to have attempted to amend their pleading to address those issues. They've simply just asked for more time. If they haven't shown an amended complaint or a proposed amended complaint that would address those issues, we think that point is uncontested and those claims should be dismissed.

Ultimately, because the proposed amended complaint that the plaintiffs have filed here has not pled the information that's required, we think these claims should be dismissed with prejudice. Plaintiffs have had their chance to plead these claims, they failed to do so, and we request a with prejudice dismissal.

Your Honor, if I may, without any further questions, I would reserve any remaining time for rebuttal.

THE COURT: Thank you.

Thank you, Mr. Altman.

MR. ALTMAN: Good afternoon, your Honor. There is a lot said by brother counsel. I'll try to address it in a

somewhat rational order.

On the preemption front, it simply doesn't apply here. What the defendants ignore, pharmacovigilance is not limited to I get a report and I send it in, and I've done my job. Much more is required. 314.80(b) requires the companies to review and analyze the adverse event information that it receives. So they don't get to just say, oh, we sent them all to the FDA, we are covered. It's much more than that. As the Supreme Court said in *Wyeth v. Levine*, responsibility for change of the label rests squarely and primarily with the manufacturer, not with the FDA.

The FDA cannot possibly -- one of the thing that's astounding, Pfizer's pharmacovigilance department is likely bigger than the entire FDA's pharmacovigilance department that's required for monitoring 5,000 drugs. So clearly, it is not the FDA's responsibility.

Defendants have put forth no evidence that they ever analyzed this information. And something that's very, very important, the dilemma is really the defendant's. Because on the one hand, with respect to the New York law, they try to say that the plaintiffs were fully on notice of the relationship between the drug and diabetes. But on the other hand, to this day they still deny that there is a relationship between the drug and diabetes.

Now, the label, one of the things, I did the analysis,

I did the analysis myself, which is a particular expertise. I'm a testifying expert in pharmacovigilance matters, and I've testified in the United States and internationally. I went and looked at the adverse event data. Pfizer to this day, I believe, when they receive a report of Lipitor and diabetes, they send it to the FDA telling the FDA this is not in our label. How can they possibly on the one hand continuously with thousands and thousands of reports tell the FDA this isn't in our label, and at the same time say that the label was adequate. It's just, that's just words. It's actions that actually speak here as to what's going on.

The fact is diabetes is not in the label. And even definitionally, 314.80(a), which describes what an unexpected adverse event is, says an event is that is either more specific or more severe than a labeled event is unexpected. And your Honor asked the right question, does HBA1c elevation equate to diabetes? It does not. They don't suggest that, they don't posit that. They are not the same thing. You can have an elevation in A1c and not have diabetes. So clearly, definitionally and by actions -- so in terms of preemption now the question comes to be -- this was the crux of *Wyeth v. Levine* which was about a drug called promethazine. The question was, the Supreme Court basically says while you may have a defense up on the day you ask the FDA to take an action, everything continues to change after that fact. You don't get

to say because the FDA said it was okay today, that that means it is all good all time going forward.

And the other interesting thing is that the defendants seem to suggest that if they didn't comply with 314.80(b), which means they reviewed the adverse event information, then you can't say there was some new information that was found. We told FDA about the reports, but even though we had to look at them, we didn't look at them, so you can't say we had new information, even though we didn't meet our obligations.

And to cut off any *Buckman* issues, labels are not written for the FDA. They are written for doctors and they are written for patients. And the primary source of changes to the label is adverse event information that comes in over time. The Supreme Court was well aware of that. You can't possibly know what a drug is going to do in the population at large just based upon clinical trials. It is something -- there is a concept called the rule of threes. If an event happens one in a thousand patient years, you need to have 3,000 patient years of exposure in your clinical trials to even have a really good chance to see one. And to detect a difference, you might need 100,000 patient years, which is far beyond what the clinical trials were. That's the purpose of pharmacovigilance. It is collecting adverse event information, and it is the synthesis of that adverse event information.

We have pled throughout the complaint that there is no

evidence that the information was synthesize. There is no information that was presented to the FDA.

One of the things that's really important is in terms of First Amendment rights in this very district. A company sued the FDA that they wanted to be able to promote their drug off label. They had received warning letters from the FDA. They had violated FDA regulations as was written, and their argument was we have a First Amendment right to distribute truthful information to doctors. Well, if they have a First Amendment right to provide truthful efficacy information to doctors, they have the same First Amendment right to provide truthful safety information to doctors. You can't have it both ways. That's very much what we see here. Pfizer wants to have it both ways.

THE COURT: Why wasn't this pharmacovigilance argument included in your complaint?

MR. ALTMAN: It is.

THE COURT: Where?

MR. ALTMAN: If you look at -- well, now, let's talk about the original complaint, and one of the -- the original complaint was written for New York State court standards. It was written a certain way. Defendants removed the case, we're here. It's a little bit unfair that a complaint that was written for New York standards that's now in federal court, that -- and procedurally the way they did it denied us the free

opportunity that typically would be available to amend the complaint based on a motion to dismiss.

THE COURT: Didn't you have 21 days after --

MR. ALTMAN: -- their answer. Which was uninformative of these issues. They raised things in their motion to dismiss, this whole preemption argument, that was made in their motion for judgment on the pleadings.

THE COURT: But they included it as an affirmative defense, didn't they?

MR. ALTMAN: To say as an affirmative defense, oh, preemption. That doesn't put you on --

THE COURT: They didn't just say preemption, though. They just didn't invoke the word. The 15th affirmative defense.

MR. ALTMAN: Your Honor, that's one paragraph. They wrote 10 pages in their motion for judgment on the pleadings. I mean, this doesn't cite to -- it says plaintiffs' claims in whole or in part. They didn't talk about the 2012 labeling change, they didn't talk about that the FDA had reviewed the situation, their position that it had all been done. None of that is here.

You know, look, your Honor, I am not trying to say they were bad people and tried to snooker the plaintiffs. That's not my point here. The point is that normally, this would have elicited a motion to dismiss, we would have seen it,

we would have had an opportunity to take the substantive issues in their motion to dismiss and amend a complaint based upon it.

Given what was here, there was no way I could have given the response that -- or the amendments to the complaint that I had proposed here which are based on sound principles.

But, with respect to the pharmacovigilance argument, in the proposed amended complaint, when we get to, for example, paragraph 89. We talk about specifically thus the requirements to review as set forth in 314.80(b). We talk about the -- sorry. Paragraph 123, we talk about the ongoing duty of pharmacovigilance. As part of its duty defendants are required to continually monitor, test and analyze data regarding safety and efficacy. This is an ongoing responsibility.

And then, at the motion for judgment on the pleadings stage, it is a little bit unfair, shall we say, that they get to say what the FDA did or didn't do. They only put in a couple of things that are available publicly, they have millions of pages internally as to what was done and said, what the FDA shared and what was done internally, which we haven't gotten. And so it just seems that it's just fundamentally unfair they get to throw a few things off the FDA website that's publicly available and say that answers the question on preemption. It doesn't.

THE COURT: Could you plead any newly acquired information on which the defendant could have updated the

label?

MR. ALTMAN: We did. You got 6,000 reports of an adverse event that's not in your label.

THE COURT: All right. But, how do you square all of that with the Second Circuit's decision in *Utts* which they said it wasn't enough to just have adverse event reports?

MR. ALTMAN: Listen, I agree that in and of itself on its face, just looking at it in a vacuum, 6,000 adverse event reports may not be enough. But I will tell you that's inconsistent with the FDA, whose position is even a single well-documented adverse event can give you all but certainty of the relationship between the drug and the adverse event.

My point is at this stage in the game, there are still at least 6,000 adverse event reports for an unlabeled event. Now, one of the things that goes along with this is there's something in the E.U. called a risk management plan which may or may not be shared with the United States. But from a causation perspective, atorvastatin, the generic form of Lipitor, has been designated an identified risk for causing diabetes. What that means, and this is in our complaint, the proposed amended complaint, is at paragraph 75, is the fact -- an identified risk is an untoward occurrence for which there is adequate evidence of an association with the medicinal product of interest. An adverse reaction adequately demonstrated in non-clinical studies confirmed by clinical data or an adverse

reaction observed in well-designed clinical trials or epidemiologic studies for which the magnitude of the difference compared with the comparator group on a parameter of interest suggests a causal relationship or an adverse reaction suggested by a number of well-documented spontaneous reports where causality is strongly suspected by temporal relationship and biological plausibility, such as anaphylactic reactions or application site reactions.

This information was not shared with doctors and patients in the United States. That is a finding that is all but a statement of general causation. Those three items there is effectively saying that this drug causes diabetes in some individuals. That was not shared with doctors and patients.

So we have, when you take, you have this massive flood of adverse events, and your Honor, this is not my first experience with drug induced adverse events. There was a drug called gabapentin, we advertised, we got 20,000 reports concerning this. Defendants seem to suggest those reports are meaningless because they are stimulated. They are not meaningless. They do put you on notice of certain information, and some of those reports that they're sending as 15-day reports came in before the -- right around the time of the labeling change or before the labeling change. So the sequencing doesn't necessarily support these are just a bunch of meaningless lawyer reports from legal complaints.

THE COURT: Can you point me to a case where adverse event reports alone can constitute newly acquired information?

MR. ALTMAN: I can't do it right off the top of my head. If your Honor would like me to do some checking on that. But it's not just a case, how about regulatory action. I mean, if the FDA takes an action based on adverse event reports, isn't that the same as saying that adverse event reports have meaning? And by the way, your Honor, the *Matrixx*, the Supreme Court *Matrixx* decision, sets forth pretty clearly as to what kind of information should be considered.

THE COURT: I'd like to see some judicial authority for the proposition that adverse event reports alone can constitute newly acquired information. And you can give me a letter on that.

MR. ALTMAN: I'll do that, your Honor. But isn't it also relevant whether it's sufficient to warrant an investigation of those adverse event reports? Because that's the problem here. They don't get to say we have an obligation to review these reports --

THE COURT: Slow down a little bit. I'm trying to process what you are saying, and I'm confident that the court reporter is also having some difficulty just getting down what you are saying. She has to listen and translate it into something.

MR. ALTMAN: I'm sorry, your Honor.

314.80(b), that's in paragraph 89, explicitly says review -- titled review of adverse drug experiences. Each applicant having an approved application under 314.50 or, in the case of a 505(b)(2) -- that doesn't really matter -- shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, post-marketing clinical trial investigations, post-marketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers.

Do they get to say, let's just say for the sake of argument all they got was 6,000 adverse event reports and they didn't do anything with them. Do they get to say we don't have any newly acquired information because we didn't meet our regulatory obligation to assess the 6,000 reports? That's a real key question here. They can't just simply say we got these reports in, and the FDA says you have to do this. Now, once again, cutting off the *Buckman* arguments, the whole purpose of pharmacovigilance is to change the label for doctors and patients, not to meet some FDA reporting requirement. 2 CFR 201.57 says the label must be changed, the warnings, when there is reasonable evidence of a causal association. Causation need not have been proved.

So the point is that where does that come from? Where

does a company learn of its duty to change a label? They learn of it by the analysis of adverse event reports.

So, coming back to your Honor, our position is that they don't just get to stop at the receipt and the transmission of the adverse event reports. They have failed to do the analysis. And for them to get away -- get out of liability, by saying, well, we didn't do the analysis we were supposed to do so you can't say that we had new information, would be ludicrous on its face. That would truly not make sense that they would be able to do that, because that would then encourage pharmaceutical companies to never do anything, other than collect and send in the adverse event reports and not do all the things they can do and they do do.

I know this from personal experience. In fact I took Pfizer's deposition in another matter last week in a completely different drug and they analyze this information.

But coming back to the motion -- so, to answer your question, your Honor, I don't know that I can find anything that says that it is just adverse event reports. But on the other hand, we are not saying it's just adverse event reports. We have, you have to look at it, but I will tell you that --

THE COURT: Right. Exactly what else is it, other than the adverse event reports?

MR. ALTMAN: The analysis of the adverse event reports, which even the FDA acknowledges is different. Even

the Supreme Court acknowledges is something different. Personal experience, your Honor, with the very drug that was the subject of *Wyeth v. Levine*. I am a member of the International Society of Pharmacoepidemiology. I actually assisted on one of the briefs for the *Wyeth v. Levine* case. In that capacity, I analyzed personally all of the amputation reports for all drugs in the FDA database. I have the whole FDA database on my laptop. I analyzed all the amputation reports, and I was able to show when you looked at it not at the individual report level, but when you looked at it compared to the other drugs, the signal that there was this problem how it was being administrated came right to the top. I presented the information at the ISPE conference. Several members of the FDA stopped by, spoke to me about my presentation where I had done this analysis, picked up copies of it, and two weeks after the event, the label was changed. So that it was a contraindication for intervenous or intra arterial administration.

So I can tell from you personal experience that the analysis -- and that's exactly what went along with *Wyeth v. Levine*. The FDA had those reports or most of them. But it's what you did when you looked at them that made all the difference in the world. When you looked at them that way, it was crystal clear that there was a problem here in the way it was being done.

So coming back to the whole argument, your Honor. I think it's premature at this time. There may come a time at the motion for summary judgment stage, where preemption may come back. Where they may be able to show we told the FDA we didn't have anything new. We met our obligations, we did what we were supposed to do, and at that time that may be the appropriate motion, and the Court will decide one way or the other. But I don't think that day is today. I don't think it's fair to just simply say that they can pick and choose a couple of things, they can pick and choose what the FDA did seven years ago as standing for all time when the company itself acknowledges that diabetes is not in the label. To this day, it's still not in the label.

With respect to the statute of limitations issue we think it's premature to bring up that issue. They are basically saying, well, because everything happens after preemption, you lose everything.

THE COURT: When were your clients diagnosed?

MR. ALTMAN: Various different times. We are not required to plead that at the pleading stage. Statute of limitations issues are a very complex question. And particularly what's going to come into play here is the state of the knowledge and the state of the art.

Now one very funny thing that's going to take place in this courtroom is while Daubert may be the standard for expert

testimony opinions in federal court, the question as to the state, the knowledge of whether there was sufficient state of the knowledge to put the clients on notice is Frye in New York.

Now one thing that the defendants jumped across before we even get there is they didn't do anything in their brief to establish that New York law and not the law of the different states apply here. It would seem to me that they've got to establish that first that New York law will apply with respect to the statute of the limitations, and that the borrowing statute in New York will apply. They didn't do that at all. So, I don't know how they get there. And that will be a choice of law analysis, and your Honor's very familiar with how that all goes down. Is there a true conflict. If there is no true conflict, then it's one thing. If there is a true conflict, which policy applies. That's something that has to be litigated and at some point down the road.

With respect to even if New York law were to apply, there are questions in terms of fraudulent concealment, which is very adequately pled. The defendants try to suggest -- this is not a circumstance where you are dealing with a contract and there is a discrete transaction and there's fraud in that discrete transaction. This is a total campaign over the entire United States involving billions of dollars' worth of advertising and magazine articles and television commercials and everything like that. And that particular context, it

would be impossible to identify each and every occurrence, etc. with what you might normally do in fraud pleading standards. We have put sufficient information here as to what the company -- we believe the company knew, when they knew, the time period in which they knew it, the kinds of communications they were making with doctors and patients, which are the people who count. The fact that our clients relied upon that information. And in that particular context, we believe this is more than sufficient pleadings.

One of the things -- and very particularly we put in there the Jarvik debacle. And I don't know if your Honor remembers this, but there was a time when Dr. Jarvik, the inventor of the artificial heart, was doing commercials for Pfizer, and it turned out this was a very controversial topic where he was making representations that led people to believe that he was prescribing Lipitor to treat people because he is a doctor, and we've put some information on that in here. But that will need to be more fully fleshed out. But certainly, that particular campaign can stand in for the proposition of fraud, fraudulent concealment, etc., or GBL 349 claim, unfair business practices within the state of New York. It was directed from New York.

I think that if you read our complaint there is, I mean, paragraph after paragraph, I went through some of them that I thought were particularly relevant to fraud issues. For

example, paragraph 40 of the proposed amended complaint. Paragraph 42, paragraph 43, paragraph 52, 53, 58, 59, 60, 62, which by the way, at the bottom it says were material to the plaintiffs' purchase of Lipitor. Plaintiffs would not have been prescribed Lipitor if plaintiffs had known that defendant's statements, representations and advertisements were deceptive, false and incomplete. So there is the direct relationship between those statements. Paragraph 64, 72, 73, 74, 76, 80. I could go on and on.

THE COURT: I got your point.

MR. ALTMAN: I just think we have -- it's not the traditional, you know, five elements, bang, bang, bang, but I think when you look at over all, I think it's certainly more than covers that which is required.

Now, as far as not responding to certain things. Obviously there was this question of whether the Court would allow the amended complaint. It seemed to be -- it did not seem to make sense to respond to some of their issues with a proposed amended complaint that we didn't know if you were going to allow. We concede that some of those things should have been -- you know, were issues with the original complaint. So, how do we, we wouldn't really be able to respond to their issues without knowing from the Court whether you would allow the amended complaint. And which is why we didn't respond to certain issues there, but those things may come out in the wash

in terms of the statute of the limitations argument, for example. And the fraud, like I said, I think there's more than an adequate fraud allegations within the complaint.

If there's no other questions.

THE COURT: All right. Thank you, counsel.

MR. ALTMAN: Thank you, your Honor.

THE COURT: Anything further, Mr. Wilson?

MR. WILSON: Yes, your Honor, if I may. Just like to briefly respond to a few of counsel's points here. Mr. Altman would like the Court to view this through the language of or the test of whether Pfizer's label was adequate. That's not the test here. This isn't a state law question of whether the label is adequate. We think it is, but the question is rather whether Pfizer had the ability to change the label after 2012, in a way that the FDA would have permitted.

Mr. Altman had a lot of speculation about how big Pfizer's pharmacovigilance department was and how much resources go into studying things. What I can tell you, your Honor, is at the time that Lipitor, this label change happened, Lipitor was the best selling drug in history, and it was also one of the most studied drugs in history. There's more information there out there about Lipitor than just about any other drug.

And so the FDA took these allegations about diabetes very seriously, it reviewed clinical trial data from multiple

clinical trials, from multiple drugs in the same category as Lipitor. It reviewed epidemiological studies, it analyzed meta analyses of all these studies together, and it ultimately issued the label that it did, which didn't find a causal connection between Lipitor and diabetes, but it did give this warning about increases in HBA1c.

THE COURT: Did the FDA consider including a warning about diabetes in the 2012 label change?

MR. WILSON: So I referenced this briefly in my opening argument. But there is a medical review that accompanied the issuance of that label change that describes in detail what the FDA considered. It's on the FDA's website and it is judicially noticeable. If it would be helpful to the Court, we would be happy to file a copy on the docket, but it does reflect that the FDA was considering the risk of diabetes, and it lists a number of studies about statins and diabetes that it considered, and then it ultimately arrived at the language that it selected, which was not to warn that Lipitor causes diabetes, but rather to warn of reports of increases in HBA1c.

THE COURT: Could you go ahead and submit that to me after the argument.

MR. WILSON: Yes, your Honor.

Mr. Altman also noted, he made allegations about what the E.U. says about Lipitor. Problem about that is that, first

of all, it's not newly acquired information not submitted to the FDA. Because the FDA is very well aware what the E.U. labeling rule is for Lipitor. In fact the E.U. and the FDA were considering this issue simultaneously, looking at the same data, cooperating with one another, and they reached slightly different conclusions about how to word things. But overall, the labeling is equivalent. It doesn't meet the newly acquired information standard.

So Mr. Altman's proposed amended complaint here, looking at both the complaint and even the issues that Mr. Altman raised in court today that aren't pled in the complaint, it's still not enough to meet newly acquired information.

Mr. Altman has 5,000 adverse event reports. In response to your Honor's question, we are not aware of any cases that hold that adverse event reports themselves are sufficient themselves to trigger the newly acquired information standard. Mr. Altman suggests that, oh, there is an analysis of adverse event reports. Well, there isn't any analysis of adverse event reports. Mr. Altman is just simply alluding to the possibility of an analysis. If the possibility of an analysis were sufficient to be newly acquired information, then you would never have preemption, because someone could always allege, oh, you could have analyzed your adverse event report data. We don't know what the analysis would have shown or what

its parameters would have been or what its outputs would have been. What it would have shown or any of the data about it, but you could have done that analysis so we get to go forward. Then there would be no preemption.

But in fact what we see is the Second Circuit issuing the *Gibbons* decision, finding similar allegations about reports insufficient; Judge Cote in the *Utts* decision finding similar allegations insufficient; Judge Dearie in *McGrath* finding similar allegations insufficient.

Mr. Altman also speculates about what Pfizer might have known or might know about Lipitor. But speculation isn't enough. Mr. Altman has to allege facts that plausibly show newly acquired information. That he hasn't done. Mr. Altman suggests that Pfizer may not have complied with FDA regulations. Once again, this is unpled and it's speculation. And ultimately, it's independently preempted under the Supreme Court's decision in *Buckman v. plaintiffs' Legal Committee*. Allegations of violations of FDA regulations are for the FDA to enforce, and they are preempted if a private citizen tries to bring a claim about them.

Finally, on the statute of limitations, we note that essentially every other Lipitor case that we received the plaintiffs plead the date of their diagnosis with diabetes, because it's important information. That hasn't been included in the complaint here.

Mr. Altman suggests that there hasn't been an adequate conflicts of law analysis, but the law is very simple here. This court's a federal court. It applies forum law and forum conflicts of law, and New York has a statute that specifically determines this, the borrowing statute, which says that the lesser period of New York law or the plaintiffs' state of residence is what applies. So here, no matter what, New York law provides the outside limit on the timeliness of plaintiffs' claims.

Mr. Altman suggests that he is alleged fraudulent concealment, but his generalized allegations in the pleading, most of which are conclusory in nature, aren't sufficient. Fraudulent concealment is the sort of issue you get, as I am sure your Honor is aware, when someone is specifically trying to convince someone not to file a lawsuit with a false representation. Mr. Altman hasn't alleged what any of the plaintiffs in this action have seen or heard from Pfizer. And a generalized allegation about a commercial many years ago involving Dr. Jarvik on other matters is not going to cut it.

If there are no further questions from the Court, your Honor, that's all I have.

MR. ALTMAN: May I have two minutes?

THE COURT: Okay. I'll give you two minutes.

MR. ALTMAN: Even if the talk about the FDA medical review, nowhere do you see anybody say that FDA would have

denied a request to add diabetes to the label, which is what is required. Just because the FDA may not have considered it, you know, may have considered it or whatever, there is nothing to say that the FDA would have rejected such a labeling change. And the question is could Pfizer have made the change. Well, number one, there is a mechanism for them to make, it's called changes being effective, I think it's talked about, but number two, once again, they have a First Amendment right to put truthful safety information in the label.

THE COURT: But, don't you have to plead newly acquired information to get to the rebuttable presumption?

MR. ALTMAN: Your Honor, there are 6,000 adverse event reports. Brother counsel is suggesting that they have an obligation to review those reports. It's not optional. What they did, how they reviewed it, is directly relevant to this case. They had an obligation to do it, and they had an obligation to report those finding to the FDA.

Like I said, they don't get to stick their head under the sand and say we didn't do what we were supposed to do and this is not a violation of an FDA regulation. If they don't get to changing the label because they don't do the analysis that's required, that's not a *Buckman* issue. The label is for the doctors and the patients, not for the FDA.

Our position is they had information in their possession to show that increased risk of diabetes, they did

not share that with doctors and patients, they still haven't to this day. And what I'd like to know is how did Pfizer know what the FDA knew or didn't know. They are not the FDA. That's the problem with these kinds of issues at the motion to dismiss or motion for judgment on the pleadings stage. That all you have is a little glimpse, a little window of what some of the things that FDA chose to make available, but we don't know what Pfizer had in its possession.

We have pled Pfizer had the affirmative obligation to review this information and nothing was done. That's in our papers. Okay. That's newly a -- you know, the 6,000 reports, they have to do more. They don't just get to say we got them, we sent them in, we're finished.

Thank you, your Honor.

THE COURT: Counsel, thank you for your arguments. Decision reserved. Have a great weekend.

MR. ALTMAN: Do you still want me to file that letter for you?

THE COURT: If you can find a case, I'd like to see it. I haven't been able to find a case, but maybe you can.

MR. ALTMAN: You know, your Honor, like I said, I think it's not as simple as that, but I'll give your Honor what I think might be helpful in that regard and do my best. Thank you for your time, and happy holidays to you and your staff.

(Adjourned)